

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
WESTERN DIVISION

WENDY CANADY, etc.,

Plaintiff,

Case No. 3:11 oe 40011

-vs-

MEMORANDUM OPINION

ORTHO MCNEIL PHARMACEUTICAL, INC.,  
et al.,

Defendant.

KATZ, J.

Ashley Rachunok experienced a pulmonary embolism after using Defendants' Ortho Evra® birth control patch. Ms. Rachunok was a minor at the time of her injury, as well as at the time this suit was filed. Therefore, Wendy Canaday, Ms. Rachunok's mother, sued Defendants on Ms. Rachunok's behalf. Plaintiff advances Oregon state law failure to warn claims, as well as sundry other tort claims. Defendants have moved for summary judgment as to Plaintiff's failure to warn claims, and for judgment on the pleadings as to the remainder of Plaintiff's claims. For the reasons that follow, Defendants' motion for summary judgment is granted in part and denied in part, and Defendants' motion for judgment on the pleadings is denied.

**I. Background**

Ms. Rachunok was first prescribed Ortho Evra® on November 11, 2009 by Hallie Goffrier, PA. at the Salem Pediatric Clinic in Oregon. Goffrier is an Oregon-licensed physician assistant and has specialized in children and adolescent medicine at the Clinic since May 2008. The record reflects that when Goffrier prescribed the Ortho Evra®, she was aware that Ortho Evra® may increase the risk of blood clots and increase the risk of pulmonary embolism. Moreover, both of these conditions were specifically warned of in the January 2008 FDA

approved Ortho Evra® package insert, which was in effect at the time Goffrier prescribed the Ortho Evra® .

On December 30, 2009, Ms. Rachunok experienced a pulmonary embolism, allegedly as a result of using the Ortho Evra®. Plaintiff subsequently filed this action in the Northern District of Ohio as part of the Ortho Evra® multidistrict litigation. Defendants now move for summary judgment and judgment on the pleadings.

## **II. Legal Standards**

### **A. Summary Judgment**

Summary judgment is appropriate where “the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). The moving party bears the initial responsibility of “informing the district court of the basis for its motion, and identifying those portions of ‘the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,’ which it believes demonstrate the absence of a genuine issue of material fact.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548, 2553, 91 L. Ed. 2d 265 (1986). The movant may meet this burden by demonstrating the absence of evidence supporting one or more essential elements of the non-movant’s claim. *Id.* at 323-25. Once the movant meets this burden, the opposing party “must set forth specific facts showing that there is a genuine issue for trial.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250, 106 S. Ct. 2505, 2541, 91 L. Ed. 2d 202 (1986) (*quoting* FED. R. CIV. P. 56(e)).

Once the burden of production has so shifted, the party opposing summary judgment cannot rest on its pleadings or merely reassert its previous allegations. It is not sufficient “simply [to] show that there is some metaphysical doubt as to the material facts.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 106 S. Ct. 1348, 1356, 89 L. Ed. 2d 538 (1986). Rather, Rule 56(e) “requires the nonmoving party to go beyond the pleadings” and present some type of evidentiary material in support of its position. *Celotex*, 477 U.S. at 324, 106 S. Ct. at 2553; *see also Harris v. General Motors Corp.*, 201 F.3d 800, 802 (6th Cir. 2000). Summary judgment must be entered “against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” *Celotex*, 477 U.S. at 322, 106 S. Ct. at 2552.

“In considering a motion for summary judgment, the Court must view the facts and draw all reasonable inferences therefrom in a light most favorable to the nonmoving party.” *Williams v. Belknap*, 154 F. Supp. 2d 1069, 1071 (E.D. Mich. 2001) (citing *60 Ivy Street Corp. v. Alexander*, 822 F.2d 1432, 1435 (6th Cir. 1987)). However, ““at the summary judgment stage the judge’s function is not himself to weigh the evidence and determine the truth of the matter,”” *Wiley v. U.S.*, 20 F.3d 222, 227 (6th Cir. 1994) (quoting *Anderson*, 477 U.S. at 249); therefore, “[t]he Court is not required or permitted . . . to judge the evidence or make findings of fact.” *Williams*, 154 F. Supp. 2d at 1071. The purpose of summary judgment “is not to resolve factual issues, but to determine if there are genuine issues of fact to be tried.” *Abercrombie & Fitch Stores, Inc. v. Am. Eagle Outfitters, Inc.*, 130 F. Supp. 2d 928, 930 (S.D. Ohio 1999). Ultimately, this Court must determine “whether the evidence presents a sufficient disagreement to require

submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.” *Anderson*, 477 U.S. at 251-52; *see also Atchley v. RK Co.*, 224 F.3d 537, 539 (6th Cir. 2000).

#### **B. Judgment on the Pleadings**

The Court construes Plaintiff’s motion to dismiss as a Fed. R. Civ. P. 12(c) motion for judgment on the pleadings.

A Fed. R. Civ. P. 12(c) motion for judgment on the pleadings is analyzed under the same standard as a Fed. R. Civ. P. 12(b)(6) motion to dismiss. *Sensations, Inc. v. City of Grand Rapids*, 526 F.3d 291, 295 (6th Cir.2008). To defeat such a motion, the complaint must state sufficient facts, accepted as true, to state a claim “that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

In deciding the motion, the Court must accept as true all of the non-movant’s factual allegations. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Thurman v. Pfizer, Inc.*, 484 F.3d 855, 859 (6th Cir. 2013). The complaint “need not contain ‘detailed’ factual allegations, [but] its ‘factual allegations must be enough to raise a right to relief above the speculative level . . . .’” *Ass’n of Cleveland Fire Fighters v. City of Cleveland, Ohio*, 502 F.3d 545, 548 (6th Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Conclusory allegations and legal conclusions masquerading as factual allegations will not suffice. *Twombly*, 550 U.S. at 555 (holding that a complaint must contain more than “a formulaic recitation of the elements of the cause of action”).

### **III. Discussion**

#### **A. Summary Judgment on Failure to Warn**

Defendants move for summary judgment on Plaintiff's failure to warn claims, arguing they are barred by Oregon's learned intermediary doctrine. The Oregon Supreme Court established the state's learned intermediary doctrine in *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522 (Or. 1974). In *McEwen*, the court explained that "the manufacturer of ethical drugs bears the . . . duty of making timely and adequate warnings to the medical profession of any dangerous side effects produced by its drugs of which it knows, or has reason to know." *Id.* at 528 (citations omitted). This duty requires the drug manufacturer "to warn the doctor, rather than the patient," though the manufacturer remains directly liable to the patient for failing to warn the doctor. *Id.* at 529; *see also Vaughn v. G.D. Searle & Co.*, 536 P.2d 1247, 1247-48 (Or. 1975) (discussing Oregon's learned intermediary doctrine under *McEwen*); *Oksenholt v. Lederle Labs.*, 656 P.2d 293, 296-97 (Or. 1982) (same).

At the outset, the Court finds that Defendants' assertion of the learned intermediary doctrine does not entitle them to summary judgment on Plaintiff's strict liability-based failure to warn claims. This is so because, as held by the Oregon Supreme Court in *Griffith v. Blatt*, 51 P.3d 1256 (Or. 2002), "Oregon's product liability statute does not create a defense to strict liability based on the learned intermediary doctrine." *Id.* at 1262. In *Griffith*, as in the instant matter, the plaintiff asserted both strict liability and negligence-based failure to warn claims related to the adverse side effects of a prescription drug. *Id.* at 1261. The plaintiff's strict liability and negligence claims in *Griffith* both met the statutory definition of "a 'product liability civil action,'" which is governed by Or. Rev. Stat. § 30.920. *Griffith*, 51 P.3d at 1261-62. After analyzing this

statute, the *Griffith* court reversed summary judgment in favor of defendants because “[n]either the text nor the context of [the product liability] statutes indicates that the legislature intended to relieve a seller from potential strict product liability on the basis of the adequacy of a manufacturer’s product warnings to another intermediary (here, the physician).” *Id.* at 1262.

Defendants attempt to distinguish *Griffith*, albeit in a cursory footnote, deep within their brief and with little explanation. (See Defs.’ Br. Supp. Mo. Summ. J., Doc. 11-13 at 11 n.20).<sup>1</sup> Defendants assert that, contrary to *Griffith*, Section 30.920 allows the learned intermediary doctrine to be applied to strict liability claims. Defendants make this assertion in reliance on the Oregon Supreme Court’s ruling in *Schmeiser v. Trus Joist Corp.*, 540 P.2d 998 (Or. 1975). Specifically, Defendants note that Section 30.920(3) directly incorporates the Restatement (Second) of Torts § 402(A), cmts. a–m (1965). Next, Defendants point out that in *Schmeiser*, the Oregon Supreme Court analyzed, *inter alia*, cmt. j to the Restatement (Second) of Torts § 402(A), and concluded that Oregon’s learned intermediary doctrine barred strict liability failure to warn claims. See *Schmeiser*, 540 P.2d at 1005 (discussing cmt. j to the Restatement (Second) of Torts § 402(A)); *id.* at 1007 (holding lower court erred in failing to grant directed verdict for defendant because learned intermediary doctrine barred plaintiff’s strict liability failure to warn claim). Defendants state that no subsequent case law has questioned *Schmeiser*’s interpretation of cmt. j, and Defendants therefore argue that this Court is bound to follow *Schmeiser* and apply the learned intermediary doctrine to Plaintiff’s strict liability claims, notwithstanding *Griffith*.

Defendants’ application of *Schmeiser* to the instant matter is inapposite. Section 30.920, which controls Plaintiff’s claims, was enacted in 1979. See *Ewen v. McLean Trucking Co.*, 706

---

<sup>1</sup>Plaintiff’s brief makes no mention of *Griffith*.

P.2d 929, 932 (Or. 1985). *Schmeiser*, on the other hand, was decided in 1975, some four years earlier. Conversely, *Griffith* was decided in 2002, after the statute was enacted. Moreover, the *Griffith* court, after analyzing comments to § 402(A), unequivocally held that “[Or. Rev. Stat. § 30.920] does not create a defense to strict liability based on the learned intermediary doctrine.” *Id.* at 1262.

Importantly, the fact that *Schmeiser* was decided before the enactment of Section 30.920 does not, on its own, negate its applicability to the instant matter. Moreover, Defendants may well be correct that no subsequent case law has questioned *Schmeiser*’s pre-statute interpretation of cmt. j. Indeed, this Court has not located any such case law. Nevertheless, when faced with an Oregon Supreme Court decision that interprets the Restatement for the express purpose of applying it to the products liability statute now at issue (*Griffith*), it would be wholly erroneous to disregard that case in favor of a contradictory decision (*Schmeiser*) that was written before the statute was enacted. *Griffith* controls, and Oregon’s learned intermediary defense does not entitle Defendants to summary judgment on Plaintiff’s strict liability-based failure to warn claims.

As to Plaintiff’s failure to warn claims that are not based on strict liability, the learned intermediary doctrine applies and Defendants’ summary judgment motion will be granted. As explained above, drug manufacturers have an obligation under Oregon’s learned intermediary doctrine to adequately warn the medical profession about a drug’s potential adverse side effects. *McEwen*, 656 P.2d at 296-97. In the instant matter, Defendants’ January 2008 FDA approved Ortho Evra® package insert—which was in effect at the time Nurse Practitioner Goffrier prescribed the Ortho Evra®—specifically warned of the exact adverse event suffered by Ms. Rachunok; namely, increased risk of blood clots and increased risk of pulmonary embolism.

Moreover, Goffrier testified at her deposition that when she prescribed Ortho Evra® for Ms. Rachunok, she was aware of these increased risks, and she further testified that she believed Ortho Evra's risks to Ms. Rachonuk were outweighed by its benefits. Therefore, Oregon's learned intermediary doctrine entitles Defendants to summary judgment on their failure to warn claims that are not based on strict liability.

**B. Judgment on the Pleadings as to Non-Failure to Warn Claims**

Defendants move for Fed. R. Civ. P. 12(c) judgment on the pleadings as to Plaintiff's claims for negligence, breach of express and implied warranty, and fraud.

At the outset, the Court notes that Defendants' reply brief claims that since Plaintiff contends that all theories of recovery are predicated on Defendants' alleged failure to warn, the learned intermediary analysis, *supra*, requires judgment on the pleadings on all claims, even on Plaintiff's non-failure to warn claims. Importantly, it is improper for Defendants to raise this issue for the first time in their reply brief. *See Scottsdale Ins. Co. v. Flowers*, 513 F.3d 546, 553 (6th Cir. 2008) (explaining reply briefs allow movant to reply to opposition's arguments, not raise new arguments in support of motion). In any event, Defendants do not provide the Court with any explanation or authority as to why non-failure to warn causes of action are barred by a doctrine designed to preclude failure to warn claims. Defendants' unsupported, passing assertion neither offers a meaningful analysis, nor a basis on which to grant judgment on the pleadings.

Defendants also move for judgment on the pleadings on grounds that Plaintiff's complaint contains insufficient factual allegations and therefore amounts to the sort of formulaic recitation of the elements precluded under *Twombly*, 550 U.S. at 555. Upon review, the Court finds Plaintiff's complaint is not violative of the Federal Rules' pleading standards. Rather, Plaintiff's complaint



states sufficient factual matter to put Defendants on notice as to the nature of her claims, and to state claims that are plausible on their face. *See* Ortho Evra Prods. Liab. Master Compl., Doc. 12-5; *see also* Fed. R. Civ. P. 8(a) (pleading must contain short plain statement of claim showing pleader is entitled to relief); *Twombly*, 550 U.S. at 555 (Rule 8(a) requires that complaint contain sufficient factual matter to establish claim that is plausible on its face); *accord Iqbal*, 556 U.S. at 678. Further, Plaintiff pleads her fraud claim with sufficient particularity to satisfy Fed. R. Civ. P. 9(b)'s heightened pleading standard.

Additionally, Defendants argue they are entitled to judgment on the pleadings as to Plaintiff's implied warranty claim because Plaintiff did not plead privity of contract with Defendants. Defendants rely on *Davis v. Homasote Co.*, 574 P.2d 1116, 1117-18 (Or. 1978), which holds that privity is required to recover economic losses in an action for breach of an implied warranty. Defendants do not reply, however, to Plaintiff's citation of *Price v. Gatlin*, 405 P.2d 502, 503 (Or. 1965), which states that "[a] purchaser . . . who has sustained personal injuries may maintain an action for damages against a manufacturer whose defective work causes bodily harm. Such a plaintiff is unembarrassed by a lack of contract privity . . . ." Moreover, further research reveals, *inter alia*, a District of Oregon case explaining that:

Oregon courts provide no direct guidance on whether a plaintiff can recover under an implied warranty theory from a remote seller for property damage. . . . [D]icta in [the Oregon Supreme Court's decision in] *Western Seed* implies that if plaintiff had suffered some damage to its land, rather than just economic damage, then the court would have reached a different outcome [i.e., privity may not have been required]. This outcome makes sense, because damage to land or property, like personal injury, is more foreseeable for a business seeking to calculate its risks before entering into a bargain.

*McFadden v. Dryvit Sys., Inc.*, No. CV-04-103-ST, 2004 WL 2278542, at \*7-\*8 (D. Or. Sept. 24, 2008) (citing *Western Seed Prod. Corp. v. Campbell*, 442 P.2d 215, 217 (Or. 1968)). As exhibited

by the foregoing, Defendants' passing reference to *Davis, supra*, does not provide a meaningful analysis of Oregon's warranty law, and leaves open too many questions for this Court to determine whether Defendants are entitled to judgment on the pleadings. Accordingly, Plaintiff's motion for judgment on the pleadings is denied.

#### **IV. Conclusion**

For the reasons stated herein, Defendants' motion for summary judgment on Plaintiff's failure to warn claims is granted in part and denied in part. (Doc. 11). Summary judgment is granted against Plaintiff's failure to warn claims that are not based on a strict liability theory. Summary judgment is denied as to Plaintiff's failure to warn claims that are based on strict liability.

Further, Defendants' motion for judgment on the pleadings is denied. (Doc. 11).

IT IS SO ORDERED.

s/ David A. Katz  
DAVID A. KATZ  
U. S. DISTRICT JUDGE